Detection of isolated hook fractures 36 months after implantation of the Ancure endograft: A cautionary note

Sasan Najibi, MD,[a] Jerilyn Steinberg, RN,[a] Barry T. Katzen, MD,[b] Gerald Zemel, MD,[b] Peter H. Lin, MD,[a] Victor J. Weiss, MD,[a] Alan B. Lumsden, MD,[a] and **Elliot L. Chaikof, MD, PhD,[a]** *Atlanta, Ga, and Miama, Fla*

Two cases of delayed (36-month) Ancure hook fracture are reported in patients who experienced a decrease in aneurysm size and no evidence of endoleak. Both devices used redesigned hooks and are otherwise identical to those devices currently used in clinical practice. Notably, hook fractures were not visualized on all abdominal radiographic views, nor were they noted on the final "institutional" report by the reviewing radiologist. Careful clinical follow-up with multiple-view abdominal radiographs remains essential for all patients treated with an endovascular graft, with particular attention directed to the integrity of the metal components. The broader clinical significance of this observation with respect to the Ancure endograft remains to be defined. (J Vasc Surg 2001;34:353-6.)

In 1993, EndoVascular Technologies, Inc, initiated a clinical trial sponsored by the Food and Drug Administration (FDA) of the EndoVascular Grafting System (EGS) for the treatment of abdominal aortic aneurysm.[1] Fixation of the endograft to the host aorta was dependent on a series of hooks located at proximal and distal extents of the graft. In the initial phase of this trial endovascular repair was successfully completed in 39 patients. However, explantation of a device, due to a persistent endoleak with aneurysm enlargement 12 months after implantation, revealed single-hook fractures of both proximal and distal attachment systems.[2] This observation prompted a review of all the plain abdominal radiographs, which identified eight additional patients with fractured attachment systems. As a consequence, additional patient enrollment in the trial was discontinued in January 1995.

In order to reduce the maximum force on any given hook, the EGS superior attachment system had been initially designed as a self-expanding cylindrical frame consisting of four sets of V-hooks for a total of eight hooks. The superior and inferior attachment systems are identical in the tube graft configuration, whereas in the bifurcated endograft, each iliac attachment system was composed of a self-expanding cylindrical frame with three metal endohooks. All of these metal components are composed of Elgiloy, an alloy of cobalt, chromium, and nickel that provides a combination of high strength, high performance, as well as fatigue and corrosion resistance.[3] Nevertheless, close analysis of the initial hook design revealed an approximately 90-degree angle that likely subjected a discrete segment of the hook to maximal stress and introduced a potential site for microcrack formation. Therefore, the hooks were redesigned with a larger radius of curvature that increased stress distribution along a larger hook segment, reducing the magnitude of the maximal stress and sites at risk for microcrack formation (Fig 1). In vitro testing performed by the manufacturer suggests that the attachment system can withstand at least 15 years of in vivo cyclic loading.[4] After the device was reengineered, the clinical trial was resumed in November 1995.

Completion of the trial and analysis of 1-year implant data led to FDA approval of the redesigned Ancure endograft (Guidant, Inc) in September 1999.[2] Overall, midterm clinical results continue to be promising with approximately 75% of patients demonstrating a reduction in aneurysm diameter of at least 5 mm 3 years after graft implantation.[5] Nevertheless, the number of carefully analyzed patients who have been followed for a substantial time period after implantation remains relatively small. Fundamentally, the long-term durability of this device and, for that matter, all other available endografts remains unknown. Indeed, metal component fractures in AneuRx and Vanguard endografts have been observed.[6-8]

From the Department of Surgery, Division of Vascular Surgery, Emory University School of Medicine and the Emory University Hospital,[a] and the Miami Cardiac and Vascular Institute.[b]

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Reprint requests: Elliot L. Chaikof, MD, PhD, 1639 Pierce Drive, Rm 5105, Department of Surgery, Emory University, Atlanta, GA 30322 (e-mail: echaiko@emory.edu).

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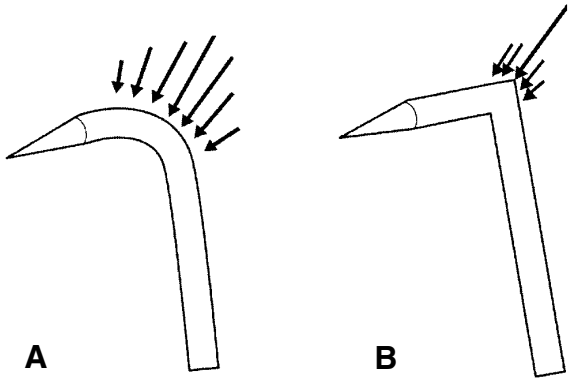

Fig 1. Schematic representation of forces exerted on endohooks: current **(A)** and initial **(B)** hook designs. *Arrows* represent qualitative estimate of force magnitude and direction.

Therefore, close scrutiny of device durability by all implanting clinicians is mandatory to determine the incidence and clinical significance of component failure. We report herein the observation in two patients of isolated hook fractures 36 months after implantation of Ancure bifurcated endografts. Both devices used redesigned hooks and are otherwise identical to those devices currently used in clinical practice.

CASE REPORT

Patient 1. A 67-year-old man with an infrarenal abdominal aortic aneurysm underwent successful exclusion with the Ancure device. The maximum aneurysm diameter was 59 mm with superior neck diameter and length of 21.9 mm and 36 mm, respectively. The aneurysm was treated with a 24-mm × 16-cm bifurcated Ancure graft. Follow-up computed tomography (CT) scans and abdominal x-ray films at 1-, 3-, 6-, 12-, and 24-month post-implant time points demonstrated relatively little change in aneurysm size, no evidence of endoleak, and an intact endograft. Abdominal CT scan and four-view abdominal x-ray films obtained 36 months after graft implantation showed a reduction of aneurysm diameter (54 mm), increased angulation, and the presence of a single endo-hook fracture of the superior attachment system (Fig 2). Neither endoleak nor device migration has been observed.

Patient 2. A 77-year-old man with an infrarenal abdominal aortic aneurysm underwent successful exclusion with the Ancure device. The maximum aneurysm diameter was 55 mm with superior neck diameter and length of 23.5 mm and 21 mm, respectively. The aneurysm was treated with a 24-mm × 16-cm bifurcated Ancure graft. Approximately 7 months after graft implantation, the patient received bilateral renal artery stents. Follow-up CT scans and abdominal x-ray films at 3-, 6-, 12-, and 24-month post-implant time points demonstrated little change in aneurysm size, no evidence of endoleak, and an intact endograft. Abdominal CT scan and four-view abdominal x-ray films obtained 36 months after graft implantation showed a reduction of aneurysm size of more than 5 mm and the presence of a single endo-hook fracture of the superior attachment system. Neither endoleak nor device migration has been observed.

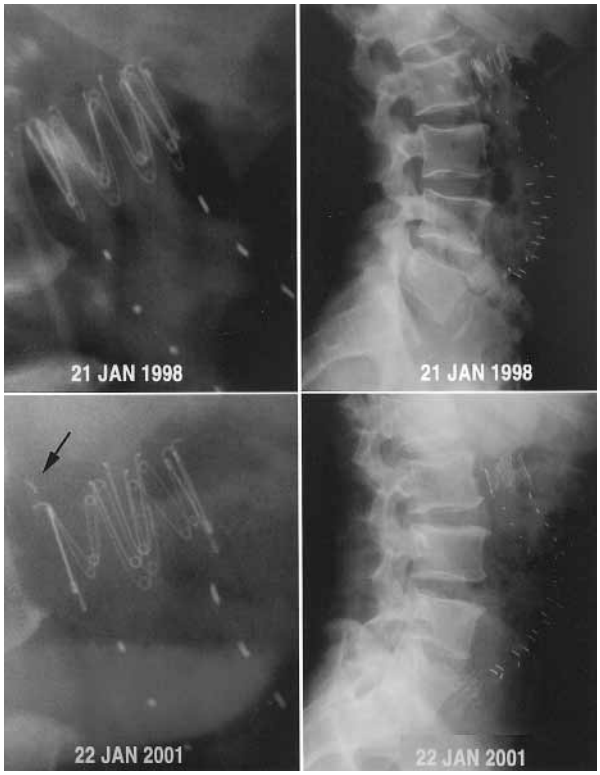

Fig 2. Abdominal x-ray films demonstrating aneurysm sac changes and a hook fracture detected 36 months after endograft implantation. *Arrow* illustrates hook fracture.

DISCUSSION

Metal components are critical constituents of all aortic endografts, serving a number of device-specific functions, including fixation of the endograft to the host aorta and provision of an adequate seal at the proximal and distal extents of the device. Among certain classes of devices, appropriate coupling of modular components and maintenance of lumen patency are also dependent on metal components. In this regard, bench models for accelerated fatigue testing are important preclinical tools for assessing acute component integrity and for providing an initial prediction of long-term endograft durability. In vitro models, however, are based on the assumption that both in vivo forces and the biological microenvironment are accurately approximated in the test system. In large measure, however, these factors remain incompletely defined for aortic endografts. Furthermore, limited clinical data exist regarding the long-term durability of endografts that is required for the validation of any predictive experimental system. Indeed, the development of accurate in vitro models for the assessment of heart valve substitutes evolved over a period of several decades through a combination of experimental, computational, and clinical investigation.[9]

The ultimate performance of any attachment system hinges on material composition, system design, and other

factors that influence the magnitude and distribution of the applied stress field, including the position of the device relative to the axis of blood flow and the host aortic wall. Elgiloy is a metal alloy that is a common component of a variety of endovascular devices, including the Ancure endograft. On the basis of conventional mechanical testing, Elgiloy has a high-yield strength and elastic modulus and is corrosion and fatigue resistant.[3] However, it is noteworthy that published material properties usually have been derived from fatigue studies of relatively large samples. For example, constant amplitude axial fatigue testing often involves the use of metal components with diameters ranging from 5 to 25 mm, and the measurement of fatigue crack growth rates has often relied on the testing of specimen bars with widths of 10 to 100 mm.[10] It is significant that the extrapolation of data obtained from large specimens to predict the behavior and mechanical properties of smaller components may yield invalid projections, a phenomenon that has been termed a *size effect*.[11] Thus, life cycle data for a given material will be accurate only when assessed in a clinically relevant configuration. This is particularly important for fine wires, which, as a consequence of material processing, may have fine grain microstructures oriented along the axis of wire that can lead to significant anisotropy in fatigue properties.

In an investigation of the durability of Elgiloy wire, Schmidt et al[10] defined a fatigue life curve for 0.78-mm diameter wire in air. Given an applied load of 22.2 N and a maximum stress at the wire apex of approximately 1500 MPa, failure was noted after 1×10^7 cycles. Studies at lower levels of applied force were not conducted. In this report, upper hooks with a wire diameter of approximately 0.4 mm fractured after 36 months (approximately 10^8 cycles). Thus, an appropriate estimation of the in vivo stress level that may have been associated with hook failure is not possible. Nevertheless, the in vivo forces that lead to hook failure were undoubtedly considerably lower than 20 N per hook. Current estimates of the physiologic loading forces on the juxtarenal segment of aortic endografts are limited with most experimental studies directed at defining the longitudinal forces required to cause endograft migration.[12,13] However, Morris et al[14] have recently developed a series of theoretical estimates of the resultant forces on the proximal portion of bifurcated endografts, as related to device diameter and iliac leg angle. For a 24-mm × 16-cm bifurcated endograft, a total force of 12 to 15 N was estimated or, in the case of an eight-hook attachment system, approximately 1.5 to 1.9 N per hook. This estimate, however, may be limited because the model did not account for neck or endograft angulation. Regardless, as an initial calculation, this work and the prior study by Schmidt et al[10] suggest that in vivo forces may be of sufficient magnitude to induce hook failure over the long-term life of the implant. Moreover, additional mechanical and chemical processes in vivo may play a significant role in microcrack initiation and propagation.[9] Further experimental and computational analysis will be essential to accurately define the physiologic stress profile on these devices and the associated fatigue life curve at relevant force levels for this and other material compositions.

It is noteworthy that the hook fractures noted in this report were not visualized on all abdominal radiographic views, nor were these fractures noted on the final "institutional" report by the reviewing radiologist. Thus, it is essential that abdominal radiographs include anteroposterior, lateral, and oblique images and that these studies be directly reviewed by the clinician responsible for patient follow-up.

Approximately 8000 Ancure devices have been implanted in the United States since FDA approval was given in September 1999. However, as of February 2001, only 167 Ancure endografts had been followed under an FDA clinical trial protocol with implant periods approaching or exceeding 36 months (Don Schwarten, Guidant Corporation, oral communication, February 2001). To date, isolated hook fractures have been detected in two (1.2%) of these 167 devices. In both cases, clinical sequelae have not been noted. However, a risk for additional hook fractures, endoleak, or device migration is present, and careful follow-up is mandatory.

CONCLUSIONS

Two cases of delayed (36-month) Ancure hook fracture are reported in patients who experienced a decrease in aneurysm size and no evidence of endoleak. Nevertheless, these events raise a risk for later endoleak or graft migration. Although initial in vitro bench models have provided reassuring estimates for device durability, these experimental systems have not been validated. Thus, patient monitoring and frequent examinations with CT or ultrasound scanning, along with multiple-view abdominal radiographs, remain essential. Particular attention should be directed to the integrity of the proximal and distal attachment sites. Further follow-up will be required to determine if the redesigned Ancure attachment system has substantially eliminated the risk of hook failure noted in the initial endograft design or simply shifted the fatigue to failure curve to a later, though clinically relevant, time point.

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Conclusion

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Jean A. Goggjns, PhD Executive Director
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